UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

١	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
_	10/820,480	04/02/2004	Claudio P. Plaza	51991/AW/W112	7287
	23363 CHRISTIE PA	⁷⁵⁹⁰ 04/05/2007 ARKER & HALE, LLP		EXAMINER	
PO BOX 7068		·	VRETTAKO ART UNIT 3739	VRETTAKOS, PETER J	
	PASADENA, CA 91109-7068			ART UNIT	PAPER NUMBER
_					
	SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
_	3 MO	NTHS	04/05/2007	PAP	PER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/820,480	PLAZA, CLAUDIO P.			
Office Action Summary	Examiner	Art Unit			
	Peter J. Vrettakos	3739			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on 09 h	Responsive to communication(s) filed on <u>09 March 2007</u> .				
2a) ☐ This action is FINAL . 2b) ☑ This	This action is FINAL . 2b)⊠ This action is non-final.				
	— · · · · · · · · · · · · · · · · · · ·				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ☑ Claim(s) 1-30 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 1-30 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	wn from consideration.				
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	ite			

DETAILED ACTION

Claims 1-30 are pending. Independent claims are 1, 15, 29, 30 each including obvious variants to a conductive porous coating as part of an electrode design with an inner non-conductive porous section.

This action is non-final. RCE filed 3-9-07.

The application is published application number: 2005/ 0222564. The publication is classified in US 606/41.

The Applicant is requested to provide (or check for accuracy) at the beginning of the Specification updated status information (serial numbers and patent numbers) of all related applications. The effective filing date of this application is 4-2-04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moaddeb et al. (6,405,078) in view of Skalsky et al. (4,844,099).

The instant application shares figures and law firm with Moaddeb.

Moaddeb discloses a catheter for mapping and stimulation of cardiac tissue with a tip electrode (36), electromagnetic sensor (64,72), temperature sensor (claim 41) and irrigation tube (38).

However, the reference is silent regarding a non-conductive porous material (sintered ceramic or sintered polyethylene) and a conductive porous coating (platinum-iridium) as claimed.

Skalsky et al. discloses an impant (see figure 24) for mapping and stimulation of cardiac tissue with a tip electrode (148a,b) and a non-conductive porous material (sintered ceramic or sintered polyethylene; 140; 60 in col. 5:56-64) and a conductive porous coating (platinum-iridium 66 in col. 6:28-32; 148).

Skalsky discloses a tip electrode (fig. 3) comprising a non-conductive porous material (60) and a conductive porous coating/electrode leaves (66). It can be fairly asserted that the non-conductive porous material is configured to avoid "substantial" contact with the tissue. (Added 3-30-07).

The combination of the two patents suggest a tip electrode catheter with a non-conductive porous material and a conductive porous coating *as claimed*. The <u>motivation</u> to combine the patents is to reduce costs due to platinum-iridium price and is found in Skalsky col. 2:34-39 where the patent mentions the high cost of stimulation electrodes

Application/Control Number: 10/820,480

Art Unit: 3739

(made of platinum iridium). This presupposes that the amount in platinum iridium in figure 24 Skalsky is appreciably less than that in figure 9 of Maddeb.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Moaddeb in view of Skalsky by integrating into the Moaddeb tip electrode design the non-conductive porous material and conductive porous coating of Skalsky. Again, the motivation to combine the patents is to reduce costs due to platinum-iridium price and is found in Skalsky col. 2:34-39 where the patent mentions the high cost of stimulation electrodes (made of platinum iridium).

The combination of the two patents makes obvious:

1. An irrigated electrode catheter (Moaddeb figure 9 and Skalsky figure 24) comprising: a catheter body (see Moaddeb figure 1) having proximal and distal ends and a lumen (Moaddeb 35) extending therethrough; a tip section (Moaddeb 36) having proximal and distal ends, the proximal end of the tip section being fixedly attached to the distal end of the catheter body (see Moaddeb figure 1); a porous tip electrode (Moaddeb 36) fixedly attached to the distal end of the tip section, the tip electrode comprising a non-conductive porous material (Skalsky figure 24 element 140) and a conductive porous (Moaddeb col. 6:52-55 – **porous** platinum-iridium) coating (Skalsky platinum-iridium 148b) adapted to cover the non-conductive porous material; and an irrigation tube (Moaddeb 38) extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the

non-conductive porous material and the conductive porous coating to reach surrounding tissue.

- 2. An irrigated electrode catheter according to claim 1, further comprising an electrode lead wire (Moaddeb 44) in electrical communication with the conductive porous coating.
- 3. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic. See Skalsky col. 5:56-65.
- 4. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises polyethylene. See Skalsky col. 5:56-65.
- 5. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating is made from material selected from the group consisting of platinum and gold. See Skalsky col. 6:28-32.
- 6. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating comprises an alloy of platinum and iridium. See Skalsky col. 6:28-32.
- 7. An irrigated electrode catheter according to claim 6, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium. See Moaddeb col. 6:54-57.

- 8. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels between particles of the non-conductive porous material. See Skalsky figure 5 elements 60 and 68.
- 9. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels of a webbing (See Skalsky "leaves") of the conductive porous coating.
- 10. An irrigated electrode catheter according to claim 1, further comprising a temperature sensing means (Moaddeb claim 41) mounted within the tip electrode.
- 11. An irrigated electrode catheter according to claim 1, further comprising an electromagnetic sensor (Moaddeb 64, 72) mounted in the tip section.
- 12. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered polymer particles. See Skalsky col. 5:56-64.
- 13. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered ceramic particles. See Skalsky col. 5:56-64.
- 14. An irrigated electrode catheter according to claim 12, wherein the polymer particles comprises particles of polyethylene or Teflon. See Skalsky col. 5:56-64.

Application/Control Number: 10/820,480

Art Unit: 3739

15. An irrigated electrode catheter (see above) comprising: a catheter body (see above) having an outer wall, proximal and distal ends, and a lumen (see above) extending therethrough; a tip section (see above) comprising a segment of flexible tubing having proximal and distal ends and at least one lumen therethrough, the proximal end of the tip section being fixedly attached to the distal end of the catheter body; a porous tip electrode (see above) fixedly attached to the distal end of the tubing of the tip section, the tip electrode having an outer surface and comprising a non-conductive porous material (see above) through which fluid can pass and a thin metal coating (aka "conductive porous coating" see above) adapted to cover the non-conductive porous material; and an irrigation tube (see above) having proximal and distal ends extending through the central lumen in the catheter body, wherein the distal end of the irrigation tube is in fluid communication with the proximal end of the passage in the tip electrode, whereby fluid can pass through the irrigation tube, into the passage in the tip electrode and through the porous material of the tip electrode to the outer surface of the tip electrode.

Page 7

16. An irrigated electrode catheter according to claim 15, further comprising an electrode lead wire (see above) in electrical communication with the thin metal coating.

,

- 17. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic. (See above.)
- 18. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises polyethylene. (See above.)
- 19. An irrigated electrode catheter according to claim 15, wherein the thin metal coating is made from material selected from the group consisting of platinum and gold. (See above.)
- 20. An irrigated electrode catheter according to claim 15, wherein the thin metal coating comprises an alloy of platinum and iridium. (See above.)
- 21. An irrigated electrode catheter according to claim 20, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium. (See above.)
- 22. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels between particles of the non-conductive porous material. (See above.)
- 23. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels of a webbing of the thin metal coating. (See above.)

Application/Control Number: 10/820,480

Art Unit: 3739

- 24. An irrigated electrode catheter according to claim 15, further comprising a temperature sensing means mounted within the tip electrode. (See above.)
- 25. An irrigated electrode catheter according to claim 15, further comprising an electromagnetic sensor mounted in the tip section. (See above.)
- 26. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered polymer particles. (See above.)
- 27. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered ceramic particles. (See above.)
- 28. An irrigated electrode catheter according to claim 26, wherein the polymer particles comprises particles of polyethylene or Teflon. (See above.)
- 29. An irrigated electrode catheter comprising: a catheter body; a tip section attached to the catheter body;
- a porous tip electrode fixedly attached to the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating generally encapsulating the non-conductive porous material;

and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. Addressed above.

30. An irrigated electrode catheter comprising: a catheter body;

a tip section attached to the catheter body; a porous tip electrode fixedly attached to the tip section, the tip electrode comprising an inner (116 is centralized in figure 16) non-conductive porous material and an outer (112c are dispersed along the outer periphery of the electrode in figure 16) conductive porous material; and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. Addressed above.

Response to Arguments

Applicant's arguments filed 6-21-06 have been fully considered but they are not persuasive.

Skalsky discloses a tip electrode (fig. 3) comprising a non-conductive porous material (60) and a conductive porous coating/electrode leaves (66). It can be fairly asserted that the non-conductive porous material is configured to avoid "substantial" contact with the tissue.

It can be fairly asserted that "substantial contact" with tissue would result if element 60 covered half or more of the tip electrode's cross section seen in figure 3. Instead, element 60 covers less than half of the tip electrode's cross section. Therefore,

it is asserted that non-conductive porous material 60 is configured to avoid substantial contact with tissue. At the very least, the above exercise should show that the ambiguous and subjective nature of the language amended into the claims (i.e. use of words such as "substantial" and "configured to") is vulnerable to a subjectively based response from the Office. As such the amended claims remain rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos March 30, 2007 ROY D. GIBSON
PRIMARY EXAMINER